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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,317

09/26/2006

Alfred R. Rudolph

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7590

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WASHINGTON, DC 20005

EXAMINER

NIEBAUER, RONALD T

ART UNIT

PAPER NUMBER

1654

NOTIFICATION DATE

DELIVERY MODE

03/16/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,317	<b>Applicant(s)</b> RUDOLPH ET AL.	
	<b>Examiner</b> RONALD T. NIEBAUER	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/23/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/09 has been entered.

Applicants amendments and arguments filed 2/16/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Previously (11/13/07) applicants elected thymosin alpha 1 as the alpha thymosin peptide, interferon alpha as the interferon, and PEG as the polymer. As discussed below, all claims are rejected. Art was found that reads on or obviates claims 33-40.

Claims 1-23 have been cancelled.

Claims 24-40 are under consideration.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 11/13/09 has been considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The 112 2<sup>nd</sup> rejection is necessitated by applicants amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 33-40** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 refers to 'a patient at high risk of exposure to SARS'. However, the distinguishing features of a patient at high risk of exposure to SARS are unclear. The specification mentions high risk (section 0012) but does not provide a specific definition of such term. The specification states that SARS seems to spread by close person-to-person contact. Thus, it is unclear if any person who may be in close contact with another person would be considered high risk. It is unclear if some type of proximity to a known case of SARS is required. For example, would only someone living in the same house of someone with SARS be considered high risk or would anyone within 10 miles or anyone on the same planet be considered at high risk. Further, it is unclear if laboratory workers who work with SARS-CoV or those who are in the military who may be exposed to biological weapons are considered 'high risk'. As such, there are multiple interpretations of high risk. The term 'high risk' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term 'high risk' is dependent on one's subjective opinion.

Claims were previously rejected under 112 1<sup>st</sup> enablement. Since the claims have been amended an updated rejection appears below.

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**Claims 24-32** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

*(1) The nature of the invention:*

The claims are drawn to methods of treating a patient with a respiratory coronavirus infection (claim 24). The claims specifically refer to those with SARS (claim 25). The agent used for treatments includes an alpha thymosin peptide.

*(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

The state of the art in treating coronavirus infection such as SARS is unpredictable. First it is noted that section 2164.05(a) states that the state of the prior art is the state at the time the application was filed. In the instant case, applicant claims benefit of provisional applications

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dating to 4/23/03. Thus the state of the art is considered as of 4/23/03. It is noted that there is limited literature available on the art up to 4/23/03. In the instant case, post-filing date references are cited to show the unpredictability in the art after the filing date.

Holmes (Journal of Clinical Investigation 2003 11:1605-1609; first cited with office action dated 12/28/07) state that (page 1607 2<sup>nd</sup> column first full paragraph) there are no approved antiviral drugs that are highly effective against coronaviruses. On page 1608 (last paragraph) Holmes states that 'development of effective drugs and vaccines for SARS is likely to take a long time'. Holmes states that 'The SARS epidemic appears to be out of control in some areas....it now appears likely that drugs and/or vaccines will be needed to control the epidemic' (page 1608 last paragraph). As such, the state of the art in treating SARS and other ailments caused by coronavirus is unpredictable

Fujii et al. (J Infect Chemother 2004 10:1-7; first cited with office action dated 12/28/07) summarize clinical reports of attempted treatment of SARS. Fujii et al. state (page 1 column 2 line 17) that 'the treatment of SARS remains largely anecdotal, and no treatment consensus has yet been reached'. In the same paragraph Fujii et al. state that 'until we have efficacious vaccines and specific anti-SARS-CoV agents, SARS is likely to remain a major health threat to the world'. As such, the state of the art in treating SARS is unpredictable.

Stockman et al., (PLOS Medicine v3 issue 9 Sept 2006 pages 1525-1531; first cited with office action dated 2/18/09) teach a systematic review of treatments of SARS (page 1525). Stockman teach that sources of the data included numerous databases and include data up to February 2005 (page 1525). Stockman conclude 'it was not possible to determine whether

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treatments benefited patients during the SARS outbreak. Some may have been harmful' (page 1525). As such, the state of the art in treating SARS is unpredictable.

The Merck Manual (on-line version [www.merck.com/mmhe](http://www.merck.com/mmhe) severe acute respiratory syndrome entry accessed Dec 2007; first cited with office action dated 12/28/07) teach (last paragraph) that doctors may treat SARS with drugs. 'However, there is no evidence that these or any other drugs are effective'. Further (last sentence), it is stated that effective treatments and preventative vaccines are still in the research stage. As such, the state of the art in treating SARS is unpredictable even as of 2007.

Taken together, the art teach that the treatment of SARS is unpredictable.

*(5) The relative skill of those in the art:*

The level of skill in the art is high.

*(2) The breadth of the claims*

The claims are drawn to methods of treating a patient with a respiratory coronavirus infection, (claim 24). The claims specifically refer to those with SARS (claim 25).

In addition to SARS, Holmes teach (page 1605 2nd column first complete paragraph) that coronaviruses are known as the cause of certain colds. Holmes teach (page 1605 last paragraph) that coronaviruses cause diseases in livestock, poultry and rodents. In addition to SARS, Holmes recites numerous other coronaviruses (page 1606 first column) including FIPV, HEV, IBV, MHV, and TGEV for example.

*(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

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The specification is void of any working examples. The specification (section 0016) states that contemplated treatments include immune-stimulating-effective amounts of the TA1 peptide. Applicants refer to prior art involving conjugating peptides to polymers (section 0025) and use of the TA1 peptide (section 0026). However, a correlation or evidence that immune-stimulation is adequate for treatment of SARS has not been provided. In fact, the teachings of Holmes, Fujii, Stockman, and The Merck Manual show unpredictability in the art for a wide range of agents.

One of skill in the art would not equate the asserted immune stimulating activity of TA1 with the ability to treat any and all coronavirus infections. Further, the specification does not provide any correlation between TA1 and their ability to treat any and all coronavirus infections. Such guidance is necessary because the prior art cited above teach that the treatment of coronavirus infections such as SARS is unpredictable. Accordingly one would be burdened with undue experimentation to determine if the peptides of the current invention could be used in methods of prevention or treatment.

It is noted that section 2164.02 of the MPEP states that working examples are factors to be considered especially for undeveloped arts. In the instant case since there is very little literature about treating SARS prior to the filing of the instant application, the treatment of SARS is considered an undeveloped art.

It is noted that section 2164.03 of the MPEP states that the amount of guidance is inversely related to the state and predictability in the art. As evidenced by the teachings of Holmes, Fujii, Stockman, and The Merck Manual, treating SARS is highly unpredictable.



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*(8) The quantity of experimentation necessary:*

Experimentation is required in numerous areas particularly related to how to use the method and determination if it would be useful for the treatment of coronavirus infections especially SARS. The claims are drawn to methods of treating a patient with a respiratory coronavirus infection, The claims specifically refer to those with SARS. Experimentation would be required to determine which, if any, coronavirus infections can be treated as claimed. Considering the state of the art as discussed by the references above, particularly with regards to the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

***Response to Arguments 112 1<sup>st</sup> enablement***

Since the claims have been amended, a new rejection adapted to the claims is recited above. Applicants arguments will be considered to the extent that they apply to the instant claims.

Applicants argue (page 5-6) that the claims have been amended.

Applicants argue that an experimental study has been attached that shows the effect on SARS lung titers.

Applicant's arguments filed 2/16/10 have been fully considered but they are not persuasive.

Although Applicants argue (page 5-6) that the claims have been amended, claims 24-32 recite 'treating a respiratory coronavirus infection'. As discussed above the teachings of Holmes, Fujii, Stockman, and The Merck Manual show high levels of unpredictability in the art. It is

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noted that section 2164.02 of the MPEP states that working examples are factors to be considered especially for undeveloped arts. In the instant case since there is very little literature about treating SARS prior to the filing of the instant application, the treatment of SARS is considered an undeveloped art. It is noted that section 2164.03 of the MPEP states that the amount of guidance is inversely related to the state and predictability in the art. As evidenced by the teachings of Holmes, Fujii, Stockman, and The Merck Manual, treating SARS is highly unpredictable.

Although Applicants argue that an experimental study has been attached that shows the effect on SARS lung titers, it is noted that the factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. Section 2164.05(a) of the MPEP states that the state of the prior art is the state at the time the application was filed. In the instant case, applicant claims benefit of provisional applications dating to 4/23/03. Thus the state of the art is considered as of 4/23/03. The study provided by applicant is dated June 26,2006. A study from June 26,2006 is not representative of the state of the art on 4/23/03. Further, the study expressly states that in the first experiments that thymosin alpha-1 did not inhibit SARS-CoV replication (page 1 paragraph 2). Such study supports the instant enablement rejection. Further, a study using mice and SARS-CoV is not commensurate in scope with 'patient' and 'respiratory

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coronavirus’ as instantly claimed. Further, the instant claims recite ‘administered at least once daily’. However, the study states that treatments were barely effective when administered prior to virus exposure (page 2). An administration prior to exposure is not representative of the instant claims which require the patient to have a coronavirus infection. Considering the state of the art as discussed by the references above, particularly with regards to the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

### ***Claim Rejections - 35 USC § 102***

The 102 rejection is necessitated by applicants amendments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 33-38,40** are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman et al. (Hepatology, v27 1998, p.1128-1135, first cited 12/28/07).

Sherman teach the administration of thymosin alpha 1 and interferon to patients (title, abstract lines 13-16, Table 2) thus meeting the agents recited in claims 33,38,40. Sherman specifically teach a dosage of 1.6 mg of thymosin alpha 1 injected subcutaneously at least once

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daily (abstract line 15, page 1129 last paragraph of first column) thus meeting the limitations of claims 33-37 of the instant claims.

Although unclear (see 112 2<sup>nd</sup>) for purposes of examination ‘high risk’ has been given its broadest reasonable interpretation such that at any patient is high risk. In the instant case, Sherman specifically teach patients with hepatitis C infection (title, abstract).

### ***Claim Rejections - 35 USC § 103***

The 103 rejection is necessitated by applicants amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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**Claims 33-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (Hepatology, v27 1998, p.1128-1135, first cited 12/28/07) and Kozlowski et al ('Improvements in protein PEGylation:pegylated interferons for treatment of hepatitis C' Journal of Controlled Release 72 (2001) 217-224)

Sherman teach the administration of thymosin alpha 1 and interferon to patients (title, abstract lines 13-16, Table 2). Sherman specifically teach a dosage of 1.6 mg of thymosin alpha 1 injected subcutaneously at least once daily (abstract line 15, page 1129 last paragraph of first column). Sherman teach thymosin alpha 1 as an immunomodulatory protein (abstract).

Sherman does not expressly teach TA1 conjugated to PEG as recited in claim 39.

Since Sherman teach administration of TA1 and interferon one would be motivated to use the teachings in the art to achieve the most efficient administration.

Kozlowski teach (abstract) that PEG has proven to be of great value for a range of biomedical applications. Kozlowski teach that a well-known method of increasing blood circulation lifetime of a protein pharmaceutical is to attach PEG to the protein (page 217). Kozlowski teach numerous benefits of PEGylation (section 2.2). Kozlowski teach PEGylation of interferon. Since Sherman teach administration of interferon and thymosin alpha 1 one would be motivated to use the teachings of Kozlowski and attach PEG to the protein pharmaceuticals. One would have a reasonable expectation of success since Kozlowski teach that PEGylation is a well-known method of increasing blood circulation lifetime of a protein pharmaceutical (page 217). Further, since Sherman teach thymosin alpha 1 as an immunomodulatory protein (abstract) one would have a reasonable expectation of success. As such, one would be motivated to administer

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PEG-thymosin alpha 1 and PEG-interferon to patients as taught by Sherman thus meeting the agents recited in claims 33,38-40. Sherman specifically teach a dosage of 1.6 mg of thymosin alpha 1 injected subcutaneously at least once daily (abstract line 15, page 1129 last paragraph of first column) thus one would be motivated to use such dose thus meeting the limitations of claims 33-37 of the instant claims.

Although unclear (see 112 2<sup>nd</sup>) for purposes of examination ‘high risk’ has been given its broadest reasonable interpretation such that at any patient is high risk. In the instant case, Sherman specifically teach patients with hepatitis C infection (title, abstract).

### ***Double Patenting***

This rejection is necessitated by applicants amendments.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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**Claims 33-37,40** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/535,835 ('835). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'835 teach the administration of an alpha thymosin peptide, specifically thymosin alpha1 (claim 2) via injection (claim 17) wherein the peptide administered at 1.6 mg (claim 5) thus meeting the limitations recited in claims 33-37,40.

Although unclear (see 112 2<sup>nd</sup>) for purposes of examination 'high risk' has been given its broadest reasonable interpretation such that at any patient is high risk.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims recited above are directed to an invention not patentably distinct from the recited claims of commonly assigned 10/535,835.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/535,835, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting

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inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

#### ***Prior art of record***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4179337 (Davis et al) teach PEGylation of polypeptides including thymosin (claim 2 for example).

US 6,309,633 (Ekwuribe et al) teach PEGylation of polypeptides including thymosin (abstract, claim 34 for example).

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/  
Examiner, Art Unit 1654